

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - I

Disinfectants Branch

IN 04-25-83 OUT 05-31-83

054 5/31/83

Dennis G. Guse

Reviewed By Dennis G. Guse Date 05-31-83

EPA Reg. No. or File Symbol 49199-R

EPA Petition or EUP No. None

Date Division Received 04-20-83

Type Product Hospital Disinfectant (Saturated Towelette)

Data Accession No(s). 249476

Product Manager 31 (Lee)

Product Name ISOTEX 70

Company Name Isotex, Inc.

Submission Purpose Resubmission for a new product with
information/questions and revised label

Type Formulation Single-use disposable towelette saturated with
ready-to-use liquid enclosed in a dispenser

<u>Active Ingredient(s):</u>	<u>%</u>
Isopropyl alcohol	63.00
Alkyl (60% C14, 30% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chloride	0.12
Alkyl (50% C12, 30% C14, 17% C16, 3% C18) dimethyl ethylbenzyl ammonium chloride	0.12

200.0 Introduction.

200.1 Use(s). See attached revised label.

200.2 Background. Refer to the previous review for this product by TSS (Efficacy), Disinfectants Branch, RD, dated 03-08-83.

FRONT PANEL

Isotex 70
Disinfecting Towelettes

Active ingredients: n-alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈) dimethyl benzyl ammonium chloride	0.12%
n-alkyl (50% C ₁₂ , 30% C ₁₄ , 17% C ₁₆ , 3% C ₁₈)dimethyl ethylbenzyl ammonium chloride	0.12%
Inert ingredients	99.76%

Meets efficacy data requirements for use on surfaces in hospital or medical environments.

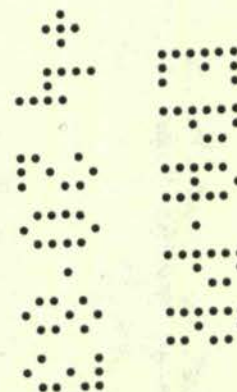
WARNING: KEEP OUT OF REACH OF CHILDREN

GERMICIDAL

EPA REG. NO. _____
EPA EST. NO. 49199-MA-01

150/5.5 x 9 in. Herbal Scented Towelettes

Net Contents; 13 fluid oz.



SIDE PANEL

PRECAUTIONARY STATEMENT

Hazards to humans and domestic animals.
Physical or chemical hazards.
Flammable. Keep away from fire or flame.

Directions for use:

To start feed: Flip open cap. Remove and discard foil seal. Remove large cover from container. From center of towelette roll, pull up a towelette corner, twist it into a point and thread it through the hole in the container cover. Pull through about one inch. Replace cover. Pull out first towelette and snap off at a 90° angle. Remaining towelettes feed automatically, ready for next use. When through using, keep small center cap closed to prevent moisture loss.

To disinfect inanimate, clean, hard, non-porous surfaces such as chairs, counters, trays, drawer pulls: Thoroughly wipe contaminated surface with wet towelette and allow it to dry. Discard towelette after use.

It is a violation of federal law to use this product in a manner inconsistent with it's labeling.

Manufactured by: Isotex, Inc., 4 Nancy Lane, Framingham, MA 01701

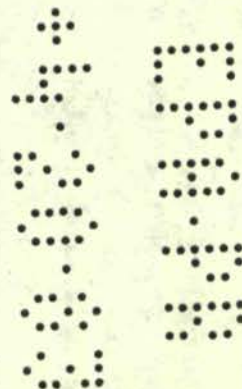
KILLS: Salmonella choleraesuis, staphylococcus aureus, pseudomonas aeruginosa.

EFFECTIVE AGAINST: Gram negative and gram positive bacteria.

DISPOSAL: Do not re-use empty container. Wrap container and put in trash collection.

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Patent Pending



TECHNICAL SUPPORT SECTION EFFICACY REVIEW - II

Disinfectants Branch

EPA Reg. No. or File Symbol 49199-R
Date Division Received 04-20-83
Data Accession No(s). 249476
Product Manager No. 31 (Lee)
Product Name ISOTEX 70
Company Name Isotex, Inc.

202.0 Recommendations.

202.1 Answers to Items in Applicant's Letter of 04-13-83.

Item #3. The information with respect to the exposure time utilized in the tests has been noted.

Item #4A. In terms of antimicrobial effectiveness, the 63% isopropanol in this product is considered an active ingredient in addition to the quaternary ammonium compounds. Deletion of the isopropanol from the product would be considered as a major formulation change which would require all microbiological efficacy data to be redeveloped on the revised formula. Deletion of any or all of the remainder of the ingredients (emollient, detergent, scent) would be considered as a minor formula change which would require some minimal efficacy data to be redeveloped on the revised formula.

Item #4B. You may not claim that the isopropanol in this product is not a disinfectant since we consider it an active ingredient from the microbiological point of view.

203.0 Labeling.

The isopropanol should be declared as an active ingredient.